UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MYLAN PHARMACEUTICALS, INC.	)	
Plaintiff,	)	
v.	)	**Civil Action No. 99-2995 (RWR)**
DONNA SHALALA, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.	)	
Defendants.	)	

MEMORANDUM OPINION

This suit challenges the validity of a Food and Drug Administration ("FDA") regulation governing the approval process for generic drugs. Plaintiff Mylan Pharmaceuticals, Inc. ("Mylan"), a generic drug manufacturer, alleges that pursuant to the regulation, the FDA has unlawfully refused to approve Mylan's application to market a generic version of a brand-name drug. Mylan sues for a declaratory judgment invalidating the regulation, and preliminary and permanent injunctions ordering the FDA to grant immediate and final approval of Mylan's application. Mylan also moves for summary judgment.[1] Because I find that the FDA's regulation is in

[1] This Court held a consolidated hearing for both the preliminary injunction and summary judgment motions on December 21, 1999.

derogation of an unambiguous statutory provision, Mylan's motion for summary judgment and request for declaratory relief will be granted. However, because the balance of the equities weighs against granting Mylan injunctive relief, Mylan's request for preliminary and permanent injunctions will be denied.

BACKGROUND

I. The Statutory and Regulatory Framework

The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq. (1994), regulates the manufacture and distribution of pharmaceuticals. Having concluded that the FDCA's cumbersome drug approval process delayed the entry of relatively inexpensive generic drugs into the market place,[2] Congress passed the so-called "Hatch-Waxman Amendments" to the FDCA in 1984. See Drug Price Competition & Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (1994)). The stated purpose of this legislation was to "make available more low cost generic drugs[.]" H.R. Rep. No. 98-857, pt. 1, at 14 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647. As Chief Judge (then Judge) Edwards of the Court of Appeals for this

[2] A generic drug contains the same active ingredients as its brand-name counterpart, but does not necessarily contain the same inactive ingredients. See Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1063 (D.C. Cir. 1998).

Circuit later explained, the Hatch-Waxman Amendments "emerged from Congress' efforts to balance two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market." Abbott Labs. v. Young, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting) (citations omitted), cert. denied, 502 U.S. 819 (1991).

In pursuit of these competing ends, the Hatch-Waxman Amendments established new guidelines for the approval of generic drugs. Generic drug makers were permitted to file an Abbreviated New Drug Application ("ANDA") which incorporated data that the "pioneer" manufacturer had already submitted to the FDA regarding the pioneer drug's safety and efficacy. In order to obtain FDA approval, the ANDA must demonstrate, among other things, that the generic drug is "bioequivalent" to the pioneer drug. 21 U.S.C. § 355(j)(2)(A)(iv). As protection for pioneer drug makers, the applicant is also required to certify in one of four ways that the generic drug will not infringe on any patent which claims the pioneer drug. See id. at § 355(j)(2)(A)(vii). The only certification of relevance in this case is the fourth and most complicated type. It permits the applicant to allege that the patent for the

pioneer drug is either invalid or will not be infringed by the marketing of the generic drug. See id. at § 355(j)(2)(A)(vii)(IV).

A generic drug manufacturer's filing of a so-called "Paragraph IV" certification has important legal ramifications. It automatically creates a cause of action for patent infringement. Upon receiving notice of a Paragraph IV certification's filing, the patent holder or pioneer manufacturer has 45 days within which to file suit against the generic manufacturer. See id. at § 355(j)(5)(B)(iii). If such an action is brought, the FDA cannot approve the generic manufacturer's ANDA for 30 months. See id. However, if the court hearing the infringement action rules before the expiration of the 30-month period that the patent at issue is "invalid or not infringed," then "the approval shall be made effective on the date of the court decision[.]" Id. at § 355(j)(5)(B)(iii)(I).

In order to encourage generic drug makers to incur the potentially substantial litigation costs associated with challenging pioneer drug makers' patents, the Hatch-Waxman Amendments provide an added incentive for generic drug producers to file Paragraph IV certifications. The first generic manufacturer to file an ANDA containing a Paragraph IV certification with respect to a specific patent is awarded a

180-day period of exclusive marketing rights for a generic version of the drug claimed by that patent. In other words, no other ANDA for the same generic drug product will be approved during those 180 days. The relevant statutory provision, clause (iv) of section 355(j)(5)(B), states:

> (iv) If the [ANDA] contains a certification described in [Paragraph IV] and is for a drug for which a previous application has been submitted under this subsection [containing a Paragraph IV] certification, the application shall be made effective not earlier than one hundred and eighty days after --
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> > (I) the date the Secretary receives notice from the applicant under the previous [ANDA] of the first commercial marketing of the drug under the previous [ANDA], or
> >
> > (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,
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> whichever is earlier.

21 U.S.C. § 355(j)(5)(B)(iv). As clause (iv) indicates, the "180-day exclusivity" awarded to the first applicant to file a Paragraph IV certification can be triggered in one of two ways -- either (1) when the generic producer begins commercial

marketing of its drug (the "commercial marketing trigger"),[3] or (2) when there is a court decision finding the pioneer drug maker's patent invalid or not infringed (the "court-decision trigger").[4] This case involves the operation of the court-decision trigger.

The FDA is charged with implementing the FDCA. The FDA determined that when the first applicant prevails at the district court level, it is in the public interest to prevent the 180-day exclusivity clock from triggering until the patent infringement litigation is ultimately resolved by the Federal Circuit.[5] The FDA therefore promulgated a regulation which provides:

> *(e) Court actions.* (1) References to actions of "the court" in paragraphs (b) and (c) of this section are to the court that enters final judgment

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[3] Though the statute states that the 180-day exclusivity period begins to run on the date that the Secretary receives notice of the marketing, the FDA has interpreted the commercial marketing trigger to run from the date that the first applicant actually commences commercial marketing. See 21 C.F.R. § 314.107(c)(1)(i) (1999). The validity of that interpretation is not at issue here.

[4] The FDA also recognizes that a court decision finding a patent to be "unenforceable" is sufficient to trigger the 180-day exclusivity. See 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

[5] See Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28,872, 28,894 (1989); Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338, 50,354-355 (1994).

> from which no appeal can be or has been taken.
>
> (2) For the purposes of establishing the effective date of approval based on a court judgment, the following dates shall be deemed to be the date of the final decision of the court on the patent issues:
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> (i) If the district court enters a decision that the patent is invalid, unenforceable, or not infringed, and the decision is not appealed, the date on which the right to appeal lapses.
>
> (ii) If the district court enters a decision that the patent is invalid, unenforceable, or not infringed, and the decision is appealed, the date of the first decision or order by a higher court holding or affirming the decision of the district court that the patent is invalid, unenforceable, or not infringed.
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> (iii) If the district court enters a decision that the patent is infringed, and the decision is appealed, the date on which the district court enters a judgment decision that the patent is invalid, unenforceable, or not infringed pursuant to a mandate issued by the court of appeals.

21 C.F.R. § 314.107(e) (1999). Thus, when a district court decision favorable to the generic manufacturer is appealed, the FDA calculates the 180-day exclusivity period from the date that the court of appeals affirms. Plaintiff contends that this interpretation of the statutory phrase "a decision of a court" is contrary to the plain meaning of the FDCA and is thus beyond the scope of the FDA's enforcement authority.

II. <u>The Factual Background of This Case</u>

This controversy stems from Mylan's attempt to obtain FDA approval for a generic capsule version of a brand-name prescription drug called Hytrin. Abbott Laboratories ("Abbott") and Geneva Pharmaceuticals, Inc. ("Geneva") have both intervened,[6] arguing that Mylan's attempt to force the FDA's hand should be rebuffed.

A. Abbott's Hytrin

Abbott developed Hytrin, which it markets in both capsule and tablet form. The active ingredient in Hytrin is a chemical compound known as terazosin hydrochloride which is used to treat hypertension and benign prostatic hyperplasia (i.e. enlarged prostate). Generic drug makers, including Geneva and Mylan, sought to market generic versions of Hytrin. These companies therefore filed ANDAs for their generic terazosin drugs, seeking to piggy-back on Abbott's research and development in the hope of obtaining relatively swift FDA approval.

B. Geneva's ANDAs and the Ensuing Geneva-Abbott Litigation

Geneva was the first generic drug manufacturer to submit ANDAs containing Paragraph IV certifications with respect to

[6] Abbott and Geneva filed unopposed motions to intervene which this Court granted on November 23, 1999.

patents claimed by Abbott for Hytrin capsules and tablets. (Declaration of Beth Brannan, Geneva's Mem. Opp. Pl.'s Mot. Prelim. Inj., Ex. B ("Brannan Decl.") at ¶¶ 4-5).[7] Upon receiving notification of Geneva's ANDAs, Abbott sued Geneva in four separate actions for patent infringement in the United States District Court for the Northern District of Illinois. (Id. at ¶ 8; Geneva's Mem. Opp. Pl.'s Mot. Prelim. Inj. at 7.) Each of these actions was eventually dismissed without prejudice, temporarily clearing the road for Geneva's march to FDA approval. (Geneva's Mem. Opp. Pl.'s Mot. Prelim. Inj. at 7.)

Geneva's path did not remain clear for long. In April, 1996, the FDA listed U.S. Patent No. 5,504,207 ("the '207 patent") as claiming Abbott's Hytrin products. (Brannan Decl. at ¶ 10.) Geneva countered by filing another ANDA on April 29, 1996, which contained Paragraph IV certifications for Hytrin tablets and capsules with respect to the '207 patent. (Declaration of Bruce Basarab, Geneva's Mem. Opp. Pl.'s Mot. Prelim. Inj., Ex. A ("Basarab Decl.") at ¶ 6.) Abbott responded by launching an infringement action based on Geneva's tablet certification, but inexplicably failed to

[7] In January, 1993, Geneva filed a Paragraph IV ANDA for generic Hytrin tablets. (Brannan Decl. at ¶¶ 3-4.) In December, 1995, Geneva filed a Paragraph IV ANDA for generic Hytrin capsules. (Id. at ¶¶ 3, 5.)

assault Geneva's capsules certification. (Id. at ¶¶ 6-7.) Accordingly, the 30-month stay on ANDA approval was triggered only with respect to Geneva's tablets application. Geneva nevertheless refrained from marketing its generic Hytrin capsules for fear that such a maneuver would unnecessarily expose Geneva to infringement liability while the battle over the tablets application was still being waged. (Id. at ¶¶ 7-8.)

On September 1, 1998, the Illinois district court granted Geneva's motion for summary judgment, declaring the '207 patent invalid with respect to Hytrin tablets. See Abbott Labs. v. Geneva Pharm., Inc., No. 96 C 3331, 1998 WL 566884 (N.D. Ill. Sept. 1, 1998). Abbott subsequently appealed that decision to the Federal Circuit. On July 1, 1999, the Federal Circuit affirmed. See Abbott Labs. v. Geneva Pharm., Inc., 182 F.3d 1315 (Fed. Cir. 1999), petition for cert. filed, 68 U.S.L.W. 3311 (U.S. Oct. 29, 1999) (No. 99-753).

As the first generic drug maker to have filed an ANDA challenging Abbott's Hytrin patents, Geneva was entitled under the Hatch-Waxman Amendments to reap the spoils of its legal victory by being awarded a 180-day exclusivity period in which to market its generic Hytrin tablets. The invalidation of the '207 patent in the tablets litigation also cleared the way for Geneva to begin marketing its generic Hytrin capsules without

fear of incurring liability for patent infringement. (Basarab Decl. at ¶ 8.) Thus, on August 13, 1999, after over six years of protracted litigation with Abbott, Geneva launched its generic Hytrin tablets and capsules onto the market. (Id. at ¶¶ 8-9.)

C. Mylan's ANDA

In the midst of the battle being waged between Geneva and Abbott, Mylan mounted its own effort to obtain FDA approval for a generic version of Hytrin. On June 6, 1997, Mylan filed an ANDA containing a Paragraph IV certification for generic terazosin capsules. (Pl.'s Stmnt. of Material Facts at ¶ 9.) Abbott then brought suit against Mylan for patent infringement on August 5, 1997, also in the United States District Court for the Northern District of Illinois. (Id. at ¶ 10.) The district court entered summary judgment for Mylan on March 4, 1999 on the basis of collateral estoppel from its finding of patent invalidity in the Abbott-Geneva tablets litigation. See Abbott Labs. v. Mylan Pharm., Inc., 37 F. Supp.2d 1076 (N.D. Ill. 1999), summarily aff'd, No. 99-1325, 1999 WL 970186 (Fed. Cir. Oct. 4, 1999).

Because Mylan was not the first generic manufacturer to have submitted an ANDA for Hytrin capsules, Mylan's legal victory did not enable it to obtain final FDA approval immediately. Instead, the FDA tentatively approved Mylan's

ANDA and indicated that final approval would be deferred until Geneva's exclusivity for Hytrin capsules expired on February 9, 2000 –- 180 days after Geneva began marketing its Hytrin capsules. (Pl.'s Stmnt. of Material Facts at ¶ 13.)[8] Mylan then commenced this action, claiming that the FDA's refusal under its regulation to grant final approval for Mylan's ANDA is unlawful because it is contrary to the plain language of the FDCA.

Mylan has moved for a preliminary injunction that would direct the FDA to approve Mylan's ANDA immediately. Mylan maintains that Geneva's market exclusivity period has already expired because the FDCA unambiguously mandates that the 180-day period be measured from the district court's entry of summary judgment in Mylan's favor on March 4, 1999, which was the first court decision of any kind invalidating the '207

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[8] The FDA calculated Geneva's exclusivity from the date that Geneva went to market because the "court-decision" trigger was never actually pulled in the Abbott-Geneva litigation with respect to Hytrin capsules. Abbott had sued only on Geneva's tablets certification. The tablet and capsule forms of the drug, however, are distinct products for FDCA purposes and are thus each eligible for their own exclusivity. See Apotex, Inc. v. Shalala, 53 F. Supp.2d 454, 463 (D.D.C.), summarily aff'd, No. 99-5231, 1999 WL 956686 (D.C. Cir. Oct. 8, 1999). Because Geneva had won a court decision invalidating Abbott's '207 patent with respect to tablets only, the FDA concluded that Geneva's exclusivity with respect to capsules was not triggered until Geneva launched its capsules on August 13, 1999, thereby pulling the commercial marketing trigger.

patent with respect to Hytrin capsules. If the exclusivity period began running on that date, 180 days would have expired on August 31, 1999. Mylan therefore maintains that it has suffered and will continue to suffer irretrievable losses in revenue for as long as Mylan's generic version of Hytrin is wrongfully kept off the market.

DISCUSSION

I. Preliminary Injunction Analysis

Mylan seeks an injunction from this Court directing the FDA to approve Mylan's ANDA immediately. To be entitled to such relief, Mylan "must show 1) a substantial likelihood of success on the merits, 2) that it would suffer irreparable injury if the injunction is not granted, 3) that an injunction would not substantially injure other interested parties, and 4) that the public interest would be furthered by the injunction." Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1066 (D.C. Cir. 1998) (internal quotations and citation omitted); see also Washington Metro. Area Transit Comm'n v. Holiday Tours, Inc., 559 F.2d 841, 843 (D.C. Cir. 1977). The D.C. Circuit has further explained that "[t]hese factors interrelate on a sliding scale and must be balanced against each other." Serono Labs., Inc. v. Shalala, 158 F.3d 1313, 1318 (D.C. Cir. 1998).

Mylan faces an additional hurdle because it seeks a mandatory injunction as opposed to a prohibitive injunction. While preliminary injunctions are typically issued to maintain the status quo until the matter can be resolved on the merits, Mylan is seeking affirmative relief that would alter the status quo by requiring the FDA to approve Mylan's ANDA immediately. In this Circuit, "the power to issue a preliminary injunction, especially a mandatory one, should be sparingly exercised." Dorfmann v. Boozer, 414 F.2d 1168, 1173 (D.C. Cir. 1969) (internal quotations and citations omitted); see also Columbia Hosp. for Women Found., Inc. v. The Bank of Tokyo-Mitsubishi, Ltd., 15 F. Supp.2d 1, 4 (D.D.C. 1997), aff'd, 159 F.3d 636 (D.C. Cir. 1998). I must therefore review Mylan's request for injunctive relief with even greater circumspection than usual in determining whether the "extraordinary writ of preliminary injunction" is warranted in this case. Boozer, 414 F.2d at 1173.

A. Substantial Likelihood of Success on the Merits

Mylan contends that the FDA's refusal to grant immediate approval of Mylan's ANDA is based on an erroneous interpretation of the Hatch-Waxman Amendments' court-decision trigger language. All parties agree that this case must be analyzed under the framework established by the Supreme Court in Chevron U.S.A., Inc. v. Natural Resources Defense Council,

Inc., 467 U.S. 837 (1984). Chevron analysis, which governs judicial review of an agency's construction of the statute it administers, consists of two discrete steps. First, the reviewing court must determine whether "Congress has directly spoken to the precise question at issue." Chevron, 467 U.S. at 842. If the answer is yes, "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." Id. at 842-43. If the answer is no because "the statute is silent or ambiguous with respect to the specific issue," the court moves on to the second step. Id. at 843. In Chevron step two, "the question for the court is whether the agency's answer is based on a permissible construction of the statute." Id.

Mylan argues that its ANDA for Hytrin capsules must be granted immediate FDA approval because "[t]he statutory language, 'a decision of a court,' plainly includes a decision of a United States district court." (Pl.'s Reply Supp. Prelim. Inj. at 7.) The FDA, Geneva, and Abbott all contend that the phrase "a decision of a court" is ambiguous and that the FDA's regulation clarifies this ambiguity in a manner that comports with the purposes of the Hatch-Waxman Amendments.

Under Chevron step one, courts are required to "exhaust the traditional tools of statutory construction" in determining whether Congress has spoken directly to the

disputed issue. Southern Cal. Edison Co. v. FERC, 195 F.3d 17, 22 (D.C. Cir. 1999) (citations omitted). In ascertaining whether the plain language of the statute is dispositive, "the court must look to the particular statutory language at issue, as well as the language and design of the statute as a whole." K Mart Corp. v. Cartier, Inc., 486 U.S. 281, 291 (1988). Accordingly, I will turn first to the relevant statutory language and then to the relationship between those words and the Hatch-Waxman Amendments' overall structure and purpose.

1. The Statutory Language

Chevron analysis often begins and ends with the statutory text because "the language of the statute itself is always the best indication of congressional intent." Abbott Labs. v. Young, 920 F.2d at 987. Clause (iv) of section 355(j)(5)(B) states that the first ANDA applicant's 180-day exclusivity is triggered on the earlier of the date that the Secretary receives notice of the first commercial marketing of the drug or the "date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed." 21 U.S.C. § 355(j)(5)(B)(iv). The pivotal question under Chevron step one is therefore whether an appealed district court decision

finding the patent at issue to be invalid or not infringed unambiguously qualifies as "a decision of a court" under the statute. Based on the plain meaning of the statutory language, the answer to that question must be yes.

The use of the indefinite article "a" plainly connotes that "a court" may refer to a district court, an appellate court, one of the two, or both.[9] The phrase could also be read to include a decision of the Supreme Court. Counsel for the FDA conceded this point at oral argument when he held up a copy of the district court's opinion from the Mylan-Abbott litigation in one hand and the Federal Circuit's affirmance in the other and professed that both were clearly decisions of a court in the Mylan-Abbott action.

The next step in the FDA's argument -- that the FDA is thereby empowered to choose which of these two decisions can trigger the exclusivity period –- is an unwarranted leap. Such an approach confuses generality for ambiguity. Simply because Congress chose to employ the indefinite article does not imply that "Congress has explicitly left a gap for the agency to fill . . . ." Chevron, 467 U.S. at 843. To the contrary, it is axiomatic that the use of broad language in a

[9] The indefinite article "a" is "1. -- [u]sed before nouns and noun phrases that denote a single, but unspecified, person or thing <*a* mountain> <*a* woman>[.]" Webster's II New Riverside University Dictionary 65 (1984).

statute "undercuts a narrow construction." United States v. James, 478 U.S. 597, 605 (1986). The natural inclusiveness of the phrase "a decision of a court" sweeps in district court decisions.[10] There is thus no textual ambiguity which would permit the FDA to preclude certain court decisions from triggering the 180-day exclusivity period.

In contending that the statute's generality creates an ambiguity, the FDA relies heavily on the Fourth Circuit's opinion in Granutec, Inc. v. Shalala, 46 U.S.P.Q.2d 1398 (4th Cir. 1998) (per curiam). The issue before the Fourth Circuit in Granutec was whether an unappealed district court's finding of non-infringement in a prior unrelated case satisfied the "court decision" requirement. See id. at 1405; Teva Pharm. USA, Inc. v. FDA, 182 F.3d 1003, 1011 (D.C. Cir. 1999) (describing Granutec). In an unpublished decision,[11] the Fourth Circuit asserted that the "FDA's reading of 'the date of a decision of a court' simply interprets ambiguous

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[10] District court decisions have res judicata and collateral estoppel effect and are binding on the parties unless a stay pending appeal is granted. See Pharmacia & Upjohn Co. v. Mylan Pharm., Inc., 170 F.3d 1373, 1381 (Fed. Cir. 1999); Deering Milliken, Inc. v. FTC, 647 F.2d 1124, 1128-29 (D.C. Cir.), cert. denied, 439 U.S. 958 (1978).

[11] As the Court of Appeals for this Circuit has noted with respect to the Granutec opinion, "the rules of the Fourth Circuit disfavor (but do not prohibit) citation of unpublished opinions . . . ." Mova, 140 F.3d at 1069 n.9.

statutory terminology . . . . [which] possesses no clear, definite meaning." Id. at 1405. The panel reasoned:

> For the purpose of measuring exclusivity under this statutory scheme, 'the date of a decision' may mean the date of a district court decision, but it also may mean -- without . . . doing harm to ordinary principles of finality and res judicata -- the date appeal rights lapse or the date a higher court renders its first decision, as FDA's regulation contemplates. Similarly, 'a court' may mean 'the court,' but it may just as well mean 'any court.' A fair reading of this statutory language does not dictate a particular interpretation.

Id. In light of this perceived ambiguity and the "complicated and sensitive nature of the statutory drug approval mechanism," the Fourth Circuit elected to defer to the FDA's interpretation of the statute. Id. at 1406.

I am not persuaded by the Fourth Circuit's reasoning. Its explanation of why "a court" is ambiguous consists of what is actually an illustration of proper interpretation of broad statutory language, followed by an unsupported conclusory assertion of ambiguity. Nowhere in its opinion does the Fourth Circuit engage in an analysis of the text and structure of the statute. Instead, the panel proclaims that a textual ambiguity exists without explaining why and then proceeds to analyze the policy implications of the FDA's interpretation of that perceived ambiguity. Id. at 1405. Based on my reading of the statute, I must respectfully disagree with the Fourth

Circuit's conclusion at least that "a court" is ambiguous on its face.

2. The Statutory Structure

The structure of the statute is not at all inconsistent with according the phrase "a decision of a court" its naturally inclusive meaning. The 180-day exclusivity provision contained in clause (iv) of section 355(j)(5)(B) must be read in conjunction with the 30-month stay provision contained in clause (iii). The regulation at issue recognizes this fundamental point by defining "court" in precisely the same way for both clauses. See 21 C.F.R. § 314.107(e) (defining all references to "court" to mean "the court that enters final judgment from which no appeal can be or has been taken.").

The chief linguistic difference between clause (iii) and clause (iv) is that the former refers "the court" while the latter refers to "a court." This difference is of no great moment in light of the interplay between the clauses. Clause (iii) provides that "if before the expiration of [the 30-month] period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision." 21 U.S.C. § 355(j)(5)(B)(iii). Clause (iv) in turn provides that the 180-day exclusivity is triggered on "the date of a decision of a court in an action

described in clause (iii)" holding the patent at issue invalid or not infringed. Id. at 21 U.S.C. § 355(j)(5)(B)(iv). An "action" for patent infringement can be brought only in district court. See 28 U.S.C. § 1338 (giving district courts original jurisdiction over patent infringement claims). The plain meaning of clause (iii) appears to require that the 30-month stay be lifted immediately upon a district court ruling that the patent at issue is invalid or not infringed. See TorPharm, Inc. v. Shalala, Civ. A. No. 97-1295, 1997 U.S. Dist. LEXIS 21983, at *9 (D.D.C. Sept. 15, 1997) (finding that the phrase "the court" in clause (iii) unambiguously refers to the district court because "[t]he natural meaning of the statute's reference to 'the court' is 'the court that decides that the patent is invalid or not infringed'"), remanded, 1998 U.S. App. LEXIS 4681 (D.C. Cir. 1998), vacated on other grounds (D.D.C. Apr. 9, 1998).[12]

Assuming that "the court" in clause (iii) is the district court, then the meaning of clause (iv)'s reference to "a court" is unambiguous. If the district court finds within the 30-month stay period that the patent is invalid or not infringed, the stay is lifted pursuant to clause (iii) and the

[12] Judge Robertson vacated his opinion on remand after the parties settled while the appeal was pending. I nevertheless find his interpretation of clause (iii) persuasive.

first applicant's 180-day exclusivity is triggered pursuant to clause (iv). If, however, the district court were to find that the patent is valid and has been infringed, the 30-month stay would remain in place. If the court of appeals were to reverse the district court, the appellate court's decision would be the triggering event. Thus, the structure of the statute suggests that clause (iv)'s reference to "a court" rather than "the court" merely accounts for the possibility that the court of appeals could be the first court to find that the patent in dispute is invalid or not infringed.

3. The Statutory Context

Stripped to its core, the FDA's argument that the statute is ambiguous arises not from the statutory language or structure, but from its concern that interpreting the statute as written would undermine the purposes of the Hatch-Waxman Amendments. See TorPharm, 1997 U.S. Dist. LEXIS 21983, at *10-*11 ("The 'ambiguity' FDA says it perceives in the statutory language arises, in my view, not from uncertainty about what the language means, but from agency discomfort with how the statute as written might operate."). The FDA has narrowed the statutory definition of "a decision of a court" on the ground that a literal application of the statute's broad language would eviscerate the 180-day exclusivity incentive. The FDA was concerned that "prudent" applicants

who prevailed at the district court level would feel compelled to delay marketing their generic drug until the patent infringement litigation was finally resolved on appeal. Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338, 50,355 (1994). Meanwhile, the 180-day exclusivity period would run while the generic manufacturer waited. Id. The FDA's rule thus seeks to eliminate the purported "Hobson's choice" that the first generic applicant would face if forced to elect between either (1) launching its generic drug while the patent litigation was still pending on appeal and thereby risk potentially significant liability if the district court's decision were overturned, or (2) holding back the drug until the appeal was decided while the 180-day exclusivity clock ticked away. (Geneva's Mem. Opp. Pl.'s Mot. Prelim. Inj. at 28.)

In this respect, the FDA and the intervenors "invoke the long-standing rule that a statute should not be construed to produce an absurd result." Mova, 140 F.3d at 1068. As the Mova case attests, this is not the first time that the FDA has attempted to correct what it perceives as potentially anomalous consequences that might result from a literal interpretation of the statutory provision at issue.[13] The rule

[13] In Mova, the D.C. Circuit struck down the FDA's so-called "successful defense" requirement, which provided that

against absurdity requires that in "rare cases [in which] the literal application of a statute will produce a result demonstrably at odds with the intentions of its drafters. . . . the intention of the drafters, rather than the strict language, controls." United States v. Ron Pair Enter., Inc., 489 U.S. 235, 242 (1989) (internal quotations and citation omitted). The D.C. Circuit has explained that "[i]n deciding whether a result is absurd," courts are to "consider not only whether that result is contrary to common sense, but also whether it is inconsistent with the clear intentions of the statute's drafters -- that is, whether the result is absurd when considered in the particular statutory context." Mova, 140 F.3d at 1068. Moreover, "[w]hen the agency concludes that a literal reading of a statute would thwart the purposes of Congress, it may deviate no further from the statute than is needed to protect congressional intent." Id.

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the first ANDA applicant to submit a Paragraph IV certification was required to "successfully defend" a patent infringement suit in order to obtain its 180-day exclusivity period. See 21 C.F.R. § 314.107(c)(1) (1998). The FDA argued that its regulation was designed to avoid the "bizarre results" that could arise if the first applicant is never sued or if the first applicant loses its suit. Mova, 140 F.3d at 1067. Though it acknowledged that the FDA's concerns were not illusory, the D.C. Circuit nevertheless struck down the regulation under Chevron step one as inconsistent with the statute's text and structure. See id. at 1069-74.

The legislative history of the Hatch-Waxman Amendments provides scant support for the FDA's absurdity argument. Because "[t]he legislative history of section 355(j)(5)(B)(iv) is limited," Mova, 140 F.3d at 1072, the parties resort to the legislative history of section 355(j)(5)(B)(iii) in support of their respective interpretations of the statute. As originally drafted, clause (iii) would have imposed an 18-month stay on approval for ANDAs containing Paragraph IV certifications. See H.R. Rep. No. 98-857, pt. 1, at 4. Furthermore, the original bill's references to court decisions were apparently understood to mean district court decisions. See id. at 27-28 (stating that "approval of the ANDA may not be made effective until 18 months after the notice of the certification was provided unless a district court has decided a case for patent infringement earlier" and that the exclusivity period commences no "sooner than 180 days after the previous applicant has begun commercial marketing, or the date on which the court holds the patent invalid or not infringed, whichever occurs first") (emphasis added).

After negotiations between the bill's backers from both houses and industry representatives, the bill was amended to extend the stay from 18 to 30 months. Congressman Waxman explained that this change was made in part because:

> The facts of life are that a generic drug manufacturer will await, as a practical matter, until the decision of a court on a patent challenge before that manufacturer markets a generic drug. That is the information they have given us as to their practice. We would expect the litigation to be resolved and, once it is resolved, it is determinative of the issue.

130 Cong. Rec. 24,427 (1984). In introducing the amendment on the Senate floor, Senator Hatch stated in like terms that extending the stay period from 18 to 30 months "increases the likelihood that the litigation will be concluded within the time period during which ANDA's are not allowed." Id. at 23,765.

According to the FDA and the intervenors, these statements by the legislation's co-authors indicate that the final bill was intended to conform to generic manufacturers' practice of waiting until a litigation is "resolved" or "concluded" before bringing their product to market. A litigation, so the argument goes, is not typically "resolved" or "concluded" in a manner that is "determinative of the issue" until the appellate court has entered its decision. Congress therefore could not have intended for the 180-day period to be triggered until appeal rights had lapsed or until the Federal Circuit had ruled.

While this interpretation of the legislative history may have some superficial appeal, it is insufficient to overcome

the plain language of the statute. Congress is well aware of how to amend a statute and it is also aware of how litigation proceeds through the federal courts. If Congress had intended to change the statute's references to court decisions to mean decisions by "the court that enters final judgment from which no appeal can be or has been taken," then the statute presumably would have been amended to reflect as much.

It is also unclear that these carefully selected excerpts from the legislative history actually support the FDA's construction of the statute. The legislative history reveals that the stay was extended from 18 to 30 months not at the request of the generic drug companies who feared losing their 180-day exclusivity, but at the urging of the brand-name drug companies who sought to protect their own market share. As Congressman Waxman explained in greater detail:

> What the 18-month or 30-month issue deals with is, should not the litigation be resolved, at what point would we allow the generic manufacturer to go on the market with the generic product anyway. The 30-month period is one that gave further assurance to the brand-name drug manufacturer that the generic drug manufacturer would not put his competitor on the market until that court decision came through.

Id. at 24,427 (emphasis added). It thus appears that the stay period was extended primarily for the benefit of the brand-name drug manufacturers who wanted to keep generic competition

off the market for as long as possible. By contrast, there is no indication that the stay period was extended for the purpose of providing first-to-file generic manufacturers with a completely risk-free environment in which to exercise their exclusivity. Nor is there any indication that the extension was based on something other than a recognition that patent litigation is often complex and could take longer than 18 months to resolve in the district court. Simply put, there is no "very clear legislative history indicating that Congress had an intent contrary to that expressed in the statute" to justify "departing from the clear language and structure of the statute." Eagle-Picher Indus., Inc. v. EPA, 759 F.2d 922, 929 (D.C. Cir. 1985).

I am also unconvinced by the FDA and intervenors' contention that interpreting the statute as written would necessarily diminish the 180-day exclusivity incentive to such an extent that the Hatch-Waxman Amendments' main goal of expeditiously providing the public with generic drugs at reasonable prices would be greatly undermined. While the 180-day exclusivity is the prime incentive for generic drug manufacturers to challenge pioneer manufacturers' patents, it also delays competition by providing an additional period in which market participation is limited. As counsel for Geneva acknowledged at oral argument, once the market is opened to

subsequent generic applicants, the ensuing price competition drives the market price of the generic drug down to near cost. By encouraging the first generic applicant to wait for the resolution of an appeal before going to market, the FDA's regulation prolongs the period in which prices remain at inflated levels. While such a result might maximize the value of the exclusivity period, it does not comport with the Hatch-Waxman Amendments central purpose of "get[ting] generic drugs into the hands of patients at reasonable prices –- fast." In re Barr Labs., Inc., 930 F.2d 72, 76 (D.C. Cir.), cert. denied, 502 U.S. 906 (1991).

Moreover, it is not at all clear that applying the statute as written would deprive the 180-day exclusivity of all of its value even though a natural reading of the statute might produce anomalous results. For instance, if a subsequent ANDA applicant were to succeed in winning a district court judgment before the first applicant, the first applicant might not be able to take advantage of its exclusivity until the 30-month stay either expired or was lifted by a district court decision in the first applicant's favor. See Granutec, 46 U.S.P.Q.2d at 1405. As the Fourth Circuit recognized, however, exclusivity periods are a transferable commodity which can be waived in favor of another generic manufacturer for a substantial price. See id.

Moreover, if the first applicant prevails in district court, the pioneer manufacturer might be willing to pay the first applicant to keep its drug off the market pending the outcome of the litigation on appeal.[14] Finally, there is nothing to prevent the first applicant from utilizing the entire 180-day exclusivity should it conclude that the risk of reversal by the Federal Circuit is relatively low.

In short, there is no reason to suppose that Congress did not mean what it said in the statute. As the D.C. Circuit has repeatedly recognized, "Under Chevron an agency may not 'avoid the Congressional intent clearly expressed in the text simply by asserting that its preferred approach would be better policy.'" Southern Cal. Edison Co., 195 F.3d at 24 (quoting Engine Mfr. Ass'n v. EPA, 88 F.3d 1075, 1089 (D.C. Cir. 1996)). Because the FDA has shown neither that the statute's unambiguous text is "demonstrably at odds" with Congressional intent nor that the text produces an incoherent regulatory

[14] Mylan has alleged that Abbott and Geneva entered into just such an agreement with respect to Geneva's generic Hytrin capsules after Geneva prevailed in district court with respect to tablets. (Pl.'s Reply Supp. Prelim. Inj. at 11 n.11.) Such agreements are certainly not unheard of. See Mova, 140 F.3d at 1072 n.14 (describing purported agreement pursuant to which pioneer agreed to pay the first generic applicant $10 million per quarter in exchange for the applicant's agreement not to sell its product before the 30-month stay expired).

scheme, the merits of this case will be resolved in Mylan's favor under Chevron step one. See infra Part II.

B. Irreparable Harm

Though Mylan has demonstrated a substantial likelihood of success on the merits, it has failed to establish that it will be irreparably harmed if injunctive relief is not issued. Mylan asserts that it will "have product packaged, labeled and ready for sale and shipment on or before January 10, 2000." (Second Declaration of Walter H. Owens, Ph.D., Attach. to Pl.'s Reply Supp. Summ. J. ("Second Owens Decl.") at ¶ 4.) At oral argument, counsel for Mylan indicated that Mylan estimates that it could earn approximately $3 million in revenue between January 10, 2000 and when the FDA plans to grant final approval of Mylan's ANDA on February 9, 2000.

Mylan's potential loss in revenue does not amount to irreparable harm under the standards set forth in this Circuit. "It is . . . well settled that economic loss does not, in and of itself, constitute irreparable harm." Wisconsin Gas Co. v. FERC, 758 F.2d 669, 674 (D.C. Cir. 1985) (per curiam). Because Mylan is alleging a non-recoverable monetary loss, it must demonstrate "that the injury [is] more than simply irretrievable; it must also be serious in terms of its effect on the plaintiff." Gulf Oil Corp. v. Department of Energy, 514 F. Supp. 1019, 1026 (D.D.C. 1981).

Courts within the Circuit have generally been hesitant to award injunctive relief based on assertions about lost opportunities and market share. See Berman v. DePetrillo, Civ. A. No. 97-70, 1997 WL 148638, at *2 (D.D.C. 1997) (noting that "the loss of a business opportunity is a purely economic injury, and economic loss alone, however substantial, does not constitute 'irreparable harm'"); Bristol-Myers Squibb Co. v. Shalala, 923 F. Supp. 212, 221 (D.D.C. 1996) (characterizing as "mere speculation" pioneer drug maker's claim that approval of generic drug would encroach on pioneer's market share and rejecting as "inconsequential" pioneer's claim that lost revenues would be irretrievable); Mead Johnson Pharm. Group v. Bowen, 655 F. Supp. 53, 56 (D.D.C. 1986) (finding that purported loss in market share was "pure speculation"), aff'd, 838 F.2d 1332 (D.C. Cir. 1988). Conversely, courts have found irreparable harm where the movant has made a strong showing that the economic loss would significantly damage its business above and beyond a simple diminution in profits. See Bracco Diagnostics, Inc. v. Shalala, 963 F. Supp. 20, 28-29 (D.D.C. 1997) (finding research and development costs incurred by plaintiff drug manufacturers were significant particularly in light of companies' small size); Express One Int'l, Inc. v. United States Postal Serv., 814 F. Supp. 87, 91 (D.D.C. 1992) (holding that bidder on government contract demonstrated

irreparable injury where loss of 10-year $1 billion contract would cause annual loss of $130 million, would impair bidder company's relationships with subcontractors, and would likely cause significant capital costs and lay-offs); McGregor Printing Corp. v. Kemp, Civ. A. No. 91-3255, 1992 WL 118794, at *5 (D.D.C. May 14, 1992) (finding that "the irretrievable monetary loss to [plaintiff] in combination with the loss in employment to [plaintiff's] employees" amounted to irreparable harm).

Of course, these authorities do not stand for the proposition that a generic drug maker never suffers irreparable harm as a result of having one of its products wrongfully kept off the market. The D.C. Circuit has recognized that generic drug makers "face continued harm [when they are] denied access to the market . . . ." Teva, 182 F.3d at 1011 n.8 (citing Byrd v. EPA, 174 F.3d 239, 244 (D.C. Cir. 1999)). The FDA itself has acknowledged that "[e]very day after the tentative approval during which the subsequent applicant can not market its product represents a lost opportunity both for the subsequent applicant and the consumer." 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42,873, 42,878 (1999). Moreover, the mere fact that Geneva and Abbott maintain that they will be irreparably harmed if Mylan is granted FDA

approval lends credence to Mylan's assertion that early market entry is critical to the success of its product. See TorPharm, 1997 U.S. Dist. LEXIS 21983 at *15.

In this case, however, two additional factors fatally undermine Mylan's allegation of irreparable harm. First, Mylan has all but conceded that its estimated lost revenues in the month between January 10 and February 9 will not cause serious damage to the company. According to its counsel, Mylan is the nation's largest generic drug manufacturer, with annual sales of approximately three-quarters of a billion dollars.[15] Thus, Mylan's estimated loss of $3 million in revenues will amount to a mere .4 percent of Mylan's total annual sales. Such a minor loss does not constitute irreparable harm. See Bristol-Myers Squibb Co., 923 F. Supp. at 221 (noting that "a loss of less than one percent of total sales is not irreparable harm.").

Second, Mylan's delay in bringing this action further undercuts its allegation of irreparable harm. In its complaint and memorandum in support of its motion for a preliminary injunction, Mylan wrongly assumed that Geneva's 180-day exclusivity for generic Hytrin capsules had expired on

[15] According to Mylan's most recent Form 10-K filed with the Securities and Exchange Commission, Mylan's total revenues for the fiscal year ending March 31, 1999 were $721,123,000. See Mylan Laboratories, Inc., 1999 Form 10-K 21 (1999).

or about March 1, 1999. (Compl. at ¶ 26; Pl.'s Mem. Supp. Prelim. Inj. at 12.) Mylan's argument was premised on its mistaken belief that Geneva's 180-day exclusivity for Hytrin capsules was triggered on September 1, 1998 -- the day that the district court entered summary judgment in Geneva's favor in the Abbott-Geneva tablets litigation. (Id.) However, the FDA, Abbott, and Geneva were all quick to point out that, because Abbott had sued Geneva on its tablets application only, the first court decision of any kind invalidating Abbott's patent over Hytrin capsules did not occur until March 4, 1999 when the district court entered summary judgment in Mylan's favor on the basis of collateral estoppel. Recognizing its error, Mylan was forced to retract its earlier contention that Geneva's exclusivity over Hytrin capsules had expired on March 1, 1999. (Pl.'s Reply Supp. Prelim. Inj. at 3.) It asserted instead that Geneva's exclusivity had expired on August 31, 1999 -- 180 days after the district court entered summary judgment in Mylan's favor in the Mylan-Abbott litigation. (Id.)

While Mylan's candor in recognizing its mistake is welcome, the fact remains that Mylan presumed at the inception of this litigation, albeit erroneously, that it was legally entitled to market generic Hytrin capsules as early as March 1, 1999. However, Mylan did not file this suit and its motion

for a preliminary injunction until November 10, 1999 -- over eight months after it believed that it had a right to launch its drug. Even under its corrected theory, Mylan would have waited for over two months before bringing this action. Though such a delay is not dispositive of the issue, it further militates against a finding of irreparable harm. See Ben Venue Labs., Inc. v. Novartis Pharm. Corp., 10 F. Supp.2d 446, 458 (D.N.J. 1998) (finding that generic drug maker's delay in bringing suit undercut drug maker's claim that immediate approval of its ANDA was required to avert irreparable harm); Delmatoff, Gerow, Morris Langhans, Inc. v. Children's Hosp. Nat'l Med. Ctr., Civ. A. No. 89–0219, 1989 WL 168856, at *3 (D.D.C. May 3, 1989) (noting in trademark infringement action that plaintiff's year-long delay in filing for preliminary injunction undermined claim that irreparable harm would result if such relief was denied).

C. Balance of Hardships

The balance of hardships also weighs against granting Mylan the injunctive relief it seeks. Any injury to Mylan "must be weighed against . . . the extent to which an injunction will substantially injure [another] party[.]" Serono Labs., 158 F.3d at 1326. Granting Mylan's request for injunctive relief would harm Geneva by depriving it of the

full benefits of exclusivity. See Mova, 140 F.3d at 1067 n.6 (noting that loss of exclusivity "suffices to show a severe economic impact" on a first applicant); Boehringer Ingelheim Corp. v. Shalala, 993 F. Supp. 1, 2-3 (D.D.C. 1997) (reasoning that any benefit to subsequent applicant by revoking exclusivity would be offset by loss to first applicant). According to its counsel's representations at oral argument, Geneva has calculated that it would lose up to $11 million in margin between January 10 and February 9 if its exclusivity were revoked. This loss would not only be due to Mylan's entrance into the market, but also to the entrance of other generic manufacturers whose ANDAs have received tentative FDA approval pending the expiration of Geneva's exclusivity.

The fact that, in my view, Geneva's exclusivity period should have expired already does not detract from the harm that Geneva would suffer if its exclusivity is revoked now. The 180-day exclusivity provision was specifically adopted to reward generic drug makers who, like Geneva, undertake the potentially time-consuming and costly efforts to establish that a pioneer drug maker's patent is wrongfully keeping generic drugs off the market. In keeping its Hytrin products off the market until the Federal Circuit ruled in the tablets litigation, Geneva relied in good faith on the FDA regulation at issue in this case -- a regulation which a federal court of

appeals had previously upheld. Notwithstanding my disagreement with the Fourth Circuit's interpretation of the statute, it would be inequitable to penalize Geneva for its reliance after it endured six years of litigation with Abbott which ultimately cleared the way for other generic manufacturers, including Mylan, to market their generic Hytrin products. The balance of harms therefore weighs against granting Mylan the injunctive relief it seeks.

D. Public Interest

The final preliminary injunction factor, the public interest, results in a wash. It is in the public interest for courts to carry out the will of Congress and for an agency to implement properly the statute it administers. On Mylan's side of the equation, the will of Congress as evinced in the statute's text suggests that Mylan was entitled to have its ANDA approved on August 31, 1999. Moreover, if Geneva's exclusivity is revoked, the price of generic Hytrin products would likely decrease, furthering the Hatch-Waxman Amendments' goal of increasing the availability of low cost generic drugs.

On the other hand, the cost of this price decrease would be borne chiefly by Geneva simply because it chose to exercise its prerogative under a then-valid FDA regulation. The Hatch-Waxman Amendments, however, clearly intend to reward Geneva

for its efforts. Thus, equitable considerations suggest that Congress' intent might not be best served by stripping Geneva of the full fruits of its labor.

On balance, Mylan cannot overcome its failure to demonstrate irreparable injury coupled with the hardship that injunctive relief would place on Geneva. Though the law favors Mylan on the merits, Mylan has not demonstrated an entitlement to injunctive relief. Accordingly, Mylan's motion for a preliminary injunction will be denied.

II. Summary Judgment Analysis

Subsequent to filing its motion for a preliminary injunction, Mylan moved for summary judgment. In its opposition to Mylan's motion for summary judgment, Geneva argued for the first time that Mylan lacks standing to bring this action and that Mylan's claim is not ripe for adjudication. Geneva has also moved for a continuance under Rule 56(f) of the Federal Rules of Civil Procedure in order to permit discovery regarding whether Mylan will be launch-ready by February 9, 2000.[16] Because I find that Mylan's claim is

[16] Rule 56(f) provides that "[s]hould it appear from the affidavits of a party opposing the motion that the party cannot for reasons stated present by affidavit facts essential to justify the party's opposition, the court . . . may order a continuance to permit affidavits to be obtained or depositions to be taken or discovery to be had or may make such other order as is just."

ripe for adjudication, that Mylan has standing, and that Mylan's interpretation of the statute is correct, Geneva's motion will be denied and Mylan's motion for summary judgment will be granted. However, because I find that the balance of equities weighs against issuing injunctive relief, Mylan's only remedy will be a declaratory judgment.

A. Standing and Ripeness

Standing consists of three discrete elements. First, Mylan must demonstrate that it has suffered an "injury in fact" which the Supreme Court has defined as a "an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical[.]" Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992) (internal quotations and citations omitted). Second, Mylan must demonstrate some "causal connection between the injury and the conduct complained of[.]" Id. Third, Mylan must show that its injury would be redressed by a ruling in its favor. See id. at 561.

Geneva puts forth a two-pronged argument that Mylan has failed to demonstrate injury in fact. First, Geneva questions whether Mylan will be able to bring its generic Hytrin capsules to market before Geneva's exclusivity is scheduled to

expire on February 9, 2000. Specifically, Geneva alleges based solely on its own experience that the process of manufacturing, packaging, and labeling launch quantities of generic terazosin capsules can take several weeks. (Geneva's Mem. Opp. Pl.'s Mot. Summ. J. at 15.) Second, Geneva argues that even if Mylan is able to bring its drug to market before February 9, such a launch might infringe on a patent that was recently issued to Geneva and "covers certain solid-filled terazosin capsules." (Id. at 14-15.) Both of Geneva's contentions are without merit.

Mylan categorically denies Geneva's allegation that Mylan will be unable to bring its Hytrin capsules to market by February 9, 2000. In response to Geneva's charge, Mylan submitted a second declaration of Dr. Walter Owens, Mylan's Executive Director of Laboratories. Dr. Owens specifically refutes Geneva's speculation that Mylan may be unable to go to market before February 9, 2000,[17] stating in no uncertain terms

[17] Dr. Owens has indicated that the FDA requires generic manufacturers to perform three "validation batch productions" of the new generic drug that are "of a commercial scale and . . . produced in the plant and equipment that will be used for commercial manufacture." (Second Owens Decl. at ¶ 3.) Dr. Owens reports that Mylan "has successfully produced validation batches of three of the four dosage forms of its [Hytrin] capsules and has current inventory of commercial quantities of the product." (Id. at ¶ 4.) He also confirms that Mylan "has labeling and packaging materials for these products in current inventory." (Id.)

that "Mylan will have product packaged, labeled and ready for sale and shipment on or before January 10, 2000." (Second Owens Decl. at ¶ 4.) Dr. Owens's factual assertions are unrebutted on the record before this Court.[18] There is thus "no genuine issue of material fact" as to whether the FDA's refusal to grant Mylan's ANDA immediate approval injures Mylan in a manner which is concrete, particularized, and actual. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). Furthermore, this alleged harm is a direct result of the FDA's refusal to approve Mylan's ANDA and would be redressed if the FDA reversed its position.

Geneva's second argument is based on pure speculation that Mylan's launch of its Hytrin capsules may infringe on a patent owned by Geneva. This case is not the appropriate forum in which to test Geneva's patent infringement theory. The mere fact that Geneva may have a private remedy against Mylan for patent infringement cannot prevent Mylan from

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[18] With respect to Geneva's Rule 56(f) motion, the Second Owens Declaration renders discovery unnecessary. Geneva's mere "desire to test and elaborate" on an affiant's testimony does not establish that discovery is warranted. Strang v. United States Arms Control and Disarmament Agency, 864 F.2d 859, 861 (D.C. Cir. 1989) (internal quotations omitted). Moreover, because I have concluded that Mylan is not entitled to injunctive relief on this record, any additional information Geneva seeks regarding Mylan's launch-readiness is immaterial to my analysis of the merits and the appropriate remedy.

challenging the FDA's interpretation of the FDCA. Cf. Bristol-Myers Squibb Co. v. Shalala, 91 F.3d 1493, 1498 (D.C. Cir. 1996) (finding that pioneer drug maker's standing to challenge FDA's allegedly unlawful approval of generic competitors' ANDAs was unaffected by the pioneer's securing of a private remedy against the first generic competitor eligible for approval). Here, Mylan's standing to challenge the FDA's action is unaffected by Geneva's possible cause of action against Mylan should Mylan proceed to market its product after successfully challenging the regulation at issue.

Geneva's argument that this case is not ripe for adjudication is based upon the same erroneous factual and legal premises as Geneva's challenge to Mylan's standing. "A claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." Texas v. United States, 523 U.S. 296, 300 (1998) (internal quotations and citation omitted). Geneva alleges that, because Mylan will not be able to bring its product to market before February 9, 2000, Mylan's cause of action is not ripe. Mylan, however, has alleged through Dr. Owens sufficient facts to demonstrate that its claim is neither abstract nor theoretical. Moreover, any private right of action Geneva may have against Mylan has no bearing on the

justiciability of Mylan's challenge to the FDA's regulation. Mylan's claim is therefore ripe for adjudication.

B. The Merits

The considerations governing my analysis of Mylan's request for a preliminary injunction apply with equal force to my determination of whether Mylan is entitled judgment as a matter of law. Summary judgment is proper when "there is no genuine issue as to any material fact and . . . the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). Summary judgment is particularly appropriate in a case such as this which involves solely a matter of statutory construction.

I have found that the FDA exceeded its authority in promulgating a regulation which is contrary to the plain meaning of the statute. The FDA's refusal to grant immediate approval of Mylan's ANDA is based on the FDA's erroneous interpretation of the phrase "a decision of a court" as contained in section 355(j)(5)(B)(iv) of the FDCA to mean "a final judgment from which no appeal can be or has been taken." The statutory language is unambiguous, and the phrase "a decision of a court" should have been construed to include the decision of a United States district court regardless of

whether that decision is appealed. Mylan's motion for summary judgment will therefore be granted.[19]

C. The Remedy

Mylan seeks both declaratory and injunctive relief. Having prevailed on the merits, Mylan is entitled to a declaratory judgment that the FDA's refusal to grant Mylan's ANDA final approval is based on an erroneous interpretation of the Section 355(j)(5)(B)(iv) of the Hatch-Waxman Amendments. However, Mylan is not entitled to permanent injunctive relief for the same reasons that it is not entitled to preliminary injunctive relief. A finding of a statutory violation does not automatically require the court to issue an injunction. See Weinberger v. Romero-Barcelo, 456 U.S. 305, 313 (1982) ("The grant of jurisdiction to ensure compliance with a statute hardly suggests an absolute duty to do so under any and all circumstances, and a federal judge sitting as chancellor is not mechanically obligated to grant an injunction for every violation of law."). Moreover, there is no clear indication in the FDCA that Congress intended to divest federal district courts of their "traditional equitable discretion" in enforcing the statute's provisions. Amoco

[19] At the consolidated motions hearing, counsel for the FDA orally cross-moved for summary judgment. That motion will be denied.

Prod. Co. v. Village of Gambell, 480 U.S. 531, 544 (1987). I will therefore exercise that discretion in determining the appropriate remedy for this statutory violation.

The equitable considerations which guided my preliminary injunction analysis also arise in the context of determining whether permanent injunctive relief is warranted. See id. at 546 n.12 ("The standard for a preliminary injunction is essentially the same as for a permanent injunction with the exception that the plaintiff must show a likelihood of success on the merits rather than actual success"); 11A Charles A. Wright et al., Federal Practice and Procedure § 2942 (2d ed. 1995). Mylan has demonstrated neither that it would suffer irreparable harm if an injunction is not issued nor that the balance of harms favors the issuance of an injunction. The public interest as defined by Congress in the FDCA does not clearly favor Mylan either. Preserving Geneva's hard-earned exclusivity in this case would effectuate the Congressional intent of rewarding first applicants for their efforts. Moreover, it would be inequitable to punish Geneva for justifiedly relying on the FDA's erroneous interpretation of the statute. Accordingly, I will not direct the FDA to approve Mylan's ANDA immediately.

CONCLUSION

The FDA has interpreted the Hatch-Waxman Amendments' court-decision trigger in a manner that is inconsistent with the statute's plain meaning. This departure from the statute's plain meaning has not been justified by a showing that a literal interpretation of the statute's text would not be reflective of Congress' true intent or would produce absurd results. Accordingly, the regulation at issue, 21 C.F.R. § 314.107(e), is invalid with respect to its interpretation of the phrase "a decision of a court" as contained in 21 U.S.C. § 355(j)(5)(B)(iv) and a declaratory judgment will be entered to that effect. I will direct the parties to submit proposed orders that suggest dates on which the judgment should be effective. However, because the balance of equities weighs against granting Mylan the injunctive relief it seeks, I will not direct the FDA to grant Mylan's ANDA final approval immediately. An Order consistent with this Opinion has been issued this same day.

ENTERED this _____ day of January, 2000.

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RICHARD W. ROBERTS
United States District Judge